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14 September 2011

Universal Biosensors

FDA Clearance to Market OneTouch Verio[®] System in the US

Universal Biosensors, Inc. (ASX: UBI) today announced that it has been advised that LifeScan has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its OneTouch Verio[®] blood glucose system.

UBI CEO, Paul Wright said, "Whilst an initial clearance to market OneTouch Verio[®] was received in February 2011, the current clearance relates to a system with a new meter which will be used in conjunction with the previously approved strips that are manufactured in our Melbourne facility."

Paul Wright noted "The FDA approval is a major milestone for Universal Biosensors and LifeScan. We have a very strong partner in LifeScan with a very strong competitive presence in the US market. LifeScan will ultimately determine when to launch the approved product in the US as part of its global rollout of OneTouch Verio[®]."

According to GlobalData⁽¹⁾, the North American Self-Monitoring Blood Glucose Market (SMBG) is dominated by LifeScan with approximately a 33% market share in 2009. GlobalData estimates that the SMBG market in US will grow from US\$2.77 billion in 2008 to reach US\$5.5 billion in 2015 or 40% of the world market with a compound annual growth rate over this period of 11%.

Ends

Enquiries: Mr Paul Wright: 03 9213 9000

(1) Source – GlobalData, Global Self Monitoring Blood Glucose Market, Published Nov 2009

About Universal Biosensors

For additional information in relation to Universal Biosensors, refer to http://www.universalbiosensors.com

Universal Biosensors is a specialist medical diagnostics company, founded in 2001, that is focused on the development, manufacture and commercialisation of a range of in vitro diagnostic tests for point-of-care use. These tests capitalise on a technology platform which uses a novel electrochemical cell that can be adapted for multiple analytes and provide for enhanced measurements in whole blood.

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Forward-Looking Statements

The statements contained in this release that are not purely historical are forward-looking statements within the meaning of the Exchange Act. Forward-looking statements in this release include statements regarding our expectations, beliefs, hopes, intentions or strategies regarding the proposed offering. All forwardlooking statements included in this release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations. We cannot assure you when, if at all, the proposed offering will occur, and the terms of any such offering are subject to change. Factors that could cause or contribute to such differences include, but are not limited to, factors and risks disclosed from time to time in reports filed with the SEC.